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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/052,855	03/31/98	BILLING-MEDEL	P 6064.US.P1

023492
ABBOTT LABORATORIES
DEPT. 377 - AP6D-2
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HM22/0104

EXAMINER	
CANELLA,K	
ART UNIT	**PAPER NUMBER**
1642	30

DATE MAILED: 01/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/052,855	Billings-Medel et al
Examiner	**Group Art Unit**
Karen Canella	1642

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3 months* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-43* is/are pending in the applicat

Of the above, claim(s) *1-9, 17-24, 26-29, 31-34, 36, and 37* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *10-16, 25, 30, 35, and 38-43* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Response to Amendment

1. Please note that the examiner to which your application is assigned at the PTO has been changed.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 10, 11, 15, 25, 30, 38 and 39 have been amended. Claims 10-16, 25, 30, 35 and 38-43 are under consideration.
4. The examiner reiterates that priority is given for the instant filing date of 3/31/98 since no clarification or explanation was given by applicant.

Claim Rejections Withdrawn

5. The rejection of claims 10-16, 30, 35, 38, 40-43 under 35 U.S.C. 112, second paragraph, is withdrawn.

6. The rejection of claims 25 and 38 under 35 U.S.C.102(e) as being anticipated by USP 5,733,748 is withdrawn.

Claim Rejections Maintained

7. The rejection of claims 10-16, 25, 30, 35 and 38-43 under 35 U.S.C. 101, because the claimed invention is not supported by either a credible, specific and substantial utility, or a well-established utility is maintained for reasons of record, specifically that the specification does not disclose any diseases or conditions known to be associated with the claimed polynucleotide sequences. Applicant argues that scientists skilled in the cancer diagnostic arts recognize that a gene product, i.e. either messenger RNA or protein, which is prevalent and highly specific to one tissue type, is extremely useful as a marker for the detection of disease in that tissue. Applicant further provides a declaration from Dr. Paula Friedman on the usefulness of tissue-specific markers. This has been considered but is not found to be persuasive. One of skill in the art would

recognize that a gene product, i.e. either messenger RNA or protein, which is prevalent and highly specific to a disease (see: Van de Vijer et al, Molecular and Cellular Biology, 1987, Vol. 7, pp. 1987), is extremely useful as a marker for the detection of disease in that tissue. On the other hand, a gene product, i.e. either messenger RNA or protein, which is prevalent and highly specific to one tissue type **could** be useful for the detection of that tissue type in metastatic lesions (see: Rajkumar et al, Mayo Clinic Proceedings, 1998, Vol. 73, pp. 533-536). However, no data is provided to teach the specificity of the detection of the claimed ESTs in clinical samples as indicative of colon disease or colon metastatic disease. On pg. 63, lines 25-33 it is stated that a CS141 probe were found a 1.4 Kb mRNA in 1 of 6 normal colon samples and in 4 of 6 cancerous colon samples. The specification also states that the Cs141 probe detected a 1.4 Kb RNA in the colon sample but not in any of the other non-colon RNA samples. However, both PCR (figure 4B) and Western Blot (figure 5) provide evidence that prostate tissue expresses CS141 as both mRNA and polypeptide. This does not constitute persuasive evidence that the ESTs corresponding to the consensus sequence of CS141 are colon specific or colon cancer specific. Thus, the specification fails to demonstrate a specific correlation between the detection of the claimed ESTs and the presence of colon cancer or any other disease. The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed nucleic acids.

8. The rejection of claims 10-16, 25, 30, 35 and 38-43 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, is maintained for reasons of record. Specifically, since the claimed invention is not supported by a specific, substantial and credible utility, one of skill in the art would not know how to use the claimed invention.

9. The rejection of claims 10-16, 25, 30, 35 and 38-43 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonable convey to one of skill in the art, that the inventor(s) had possession of the claimed invention at the time the application was filed, is maintained for reasons of record. Applicant argues that amendment of the claim language deleting "fragments" obviate this rejection. This has been considered but not found persuasive. The claims are drawn to polynucleotide sequences which are 90% identical to SEQ ID NO:1-9, 12 or 13, or a method of producing a polypeptide having at least 90% identity with SEQ ID NO:24-28 from the recombinant expression of polynucleotides. Thus the claims encompass non-disclosed polynucleotide sequences which differ from the disclosed polynucleotide sequences. thereof.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed. (See page 1117). The specification does not clearly allow persons of ordinary skill in the art to recognize that the applicant(s) invented what is claimed. (See Vas-Cath at page 1116).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115). With the exception of SEQ ID NO:1-9, 12, 13, or polynucleotides encoding SEQ ID NO:24-28 and degenerative coding sequences thereof, the skilled artisan cannot envision the detailed structure of the encompassed polynucleotides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Lts., 18 USPQ2d 1016.

Furthermore, In The Regents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that an adequate written description of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.

The written description in this case only sets forth SEQ ID NO:1-9, 12 or 13 and polynucleotides encoding SEQ ID NO: 24-28 therefore the written description is not commensurate in scope with the claims drawn to variants of SEQ ID NO:1-9, 12 and 13 and variants of polynucleotides encoding SEQ ID NO:24-28 beyond degenerate coding sequences. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

New claim Rejections

10. In the event that Applicants might be able to overcome the 35 USC 101 rejection above, the specification would still be enabling only for claims limited to the polynucleotides of SEQ ID NO:1-9, 12 or 13 and polynucleotides encoding SEQ ID NO: 24-28 and degenerate coding sequences thereof, and the complete complement of said, and a method of producing a polypeptide comprising SEQ ID NO:24-28 because the specification does not reasonably provide enablement for polynucleotides having at least 90% identity to SEQ ID NO:1-9, 12 or 13 and polynucleotides encoding amino acid sequences having at east 90% identity to SEQ ID NO: 24-28. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with

these claims As discussed above, the specification does not teach how to use the polynucleotides of SEQ ID NO:1-9, 12 or 13 and polynucleotides encoding SEQ ID NO: 24-28. Clearly, since the specification has not taught how to use said polynucleotides, the specification has not enabled the scope of claims 10-16, 25, 30, 35 and 38-43. When given the broadest reasonable interpretation, the claims are clearly intended to encompass a variety of species, a substantial number of which would not share either structural or functional properties with polynucleotides of SEQ ID NO:1-9, 12 or 13 or polynucleotides encoding SEQ ID NO: 24-28. Further, the specification has not shown that variant polynucleotides of SEQ ID NO:1-9, 12 or 13 and polynucleotides encoding variants of SEQ ID NO: 24-28 are capable of functioning as that which is suggested. Protein chemistry is probably one of the most unpredictable areas of biotechnology. For example, replacement of a single lysine reside at position 118 of acidic fibroblast growth factor by glutamic acid led to the substantial loss of heparin binding, receptor binding and biological activity of the protein (Burgess et al. J of Cell Bio. 1990, Vol. 111, pp. 2129-2138). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen (Lazar et al. Molecular and Cellular Biology, 1988, Vol. 8, pp. 1247-1252). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification will often dramatically affect the biological activity and characteristic of a protein. Clearly, it could not be predicted that the variant polynucleotides having at least 90% identity to SEQ ID NO:1-9, 12 or 13, or a variant polynucleotides encoding a polypeptide having 90% identity to SEQ ID NO:24-28 will function as suggested. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to make/use polynucleotides, or variants thereof that encode variant polypeptides. In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
December 28, 2000